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10/571,582	03/10/2006	Kouichi Kitahata	1422-0712PUS1	9795
2292 7590 09/13/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
ORWIG, KEVIN S				
ART UNIT		PAPER NUMBER		
1611				
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09/13/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/571,582

Applicant(s)

KITAHATA ET AL.

Examiner

Kevin S. Orwig

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-14, and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-14 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendments and arguments filed Jul. 16, 2010 are acknowledged and have been fully considered. Claims 1-4, 7-14, and 18-23 are now pending. Claims 5, 6, and 15-17 are cancelled; claims 1-4 and 7-14 are amended; claims 18-23 have been added. Claims 1-4, 7-14, and 18-23 are now under consideration.

OBJECTIONS/REJECTIONS WITHDRAWN

The rejections of claims 6 and 15-17 are moot, in light of their cancellations.

The rejection of claims 1-4, 6, 8, 9, 11, and new claim 16 under 35 U.S.C. 102(b) over SHIO is withdrawn in light of the claim amendments.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claims 1, 2, 7, 10, and 12-14 under 35 U.S.C. 103(a) is maintained as discussed below.

The double patenting rejections of record have been maintained as no action regarding these rejections has been taken by applicants at this time.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 8, 9, 11, and new claims 18, 19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over SHIO (WO 98/14399, Published Apr. 9, 1998; as evidenced by U.S. 6,511,668).

WO 98/14399 to Shio is published in Japanese. Thus, the patent resulting from the national stage entry of the international application is used herein as an English language equivalent. Column and line numbers refer to the '668 patent.

1. Shio discloses mesoporous silica and associated compositions that are useful as a carrier for cosmetics, pharmaceutical drugs and perfumes (abstract; col. 2, lines 24-34; col. 5, lines 57-59; Table 2; claim 1). Shio's compositions are obtained by a process comprising dissolving a silicate in the presence of a cationic surfactant (i.e. an organic raw material) (abstract; col. 2, lines 35-40; col. 5, lines 28-41 and 60-67). Shio teaches the use of sodium silicate (pars. [0071] and [0072]; Table 1). Shio teaches that X-ray diffraction studies showed a hexagonal structure for the silica pores (Figs. 9, 12, 13, and 18; col. 20, lines 48-52), which is completely consistent with the data provided by applicants in the rule 132 affidavit submitted Feb. 26, 2009 to illustrate this very property (compare '668 Fig. 9 with Fig. 3 of the affidavit). Shio teaches an embodiment wherein the mesoporous powder holds a perfume (i.e. a volatile substance) (title; abstract; Fig. 21; col. 1, lines 62-65; col. 3, lines 32-34; col. 23, line 57 to col. 24, line 52; claim 27). Shio teaches that the inventive silicas have a specific surface area of 900-1100 m²/g (Table 5). The pore volume is taught to be 0.51-2.32 cm³ (Table 6). Shio teaches that mesoporous powders can have pore sizes between 20-300 nm and that the disclosed silicas have a pore size of 30-35 Å (3-3.5 nm) (Table 5; col. 1, lines 16-19; Figs. 11 and

15). Shio teaches an average particle diameter of 20-200 nm is preferred, but teaches that the particle size of the powder can be adjusted with extreme ease (col. 2, lines 11-15; claim; col. 23, lines 55-56). Shio also establishes the particle size as a result effective variable since the particle size and amount of the powder correlates with the feel of the powder (col. 17, lines 39-41). Furthermore, the particles of Shio may be rod-shaped, and the long axis of the particles, while not discussed by Shio, is likely to fall within the broad range of particle size instantly claimed, absent evidence to the contrary (see, for example, Fig. 8).

2. While the particle size taught by Shio is slightly outside the instantly claimed particle size range, the porous powders of Shio have all the same properties as those purported for the instant invention. The MPEP states that "a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)". See MPEP § 2144.05. In this case, no evidence of unexpected results (nor of any claimed properties lacking in the Shio material) has been presented. Thus, it can only be expected that the material of Shio has the same properties as that having the ranges instantly claimed.

3. Regarding claim 2, Shio teaches cosmetic preparations comprising the porous silicas of the invention and teaches that the silica powders can be compounded as an emulsion or dispersion and further teaches that other ingredients generally compounded into external preparations, such as surfactants (i.e. emulsifiers) can be compounded

with the invention (col. 14, lines 28-51). See also Compounding Examples 4-12, 4-13, 4-16, 4-17, and 15), which are all cosmetic compositions using emulsifiers such as various fatty acid esters.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the instantly claimed pore and particle sizes are different than those taught by Shio and argue unexpected results (response, p. 5-6).

First, as noted above, Shio teaches a range of pore sizes that overlaps with that instantly claimed in claim 1, contrary to applicants' assertion. Thus, a *prima facie* case of obviousness exists for this range. See MPEP § 2144.05(I). Regarding the instantly claimed particle size and the pore size recited in claim 3, applicants have attempted to distinguish over Shio by picking and choosing various values from their disclosure to arrive at ranges slightly outside that taught by Shio. While such picking and choosing of endpoints for claimed ranges might be technically permissible (See MPEP § 2163.05(III)), it must be remembered that the ranges originally disclosed by applicants were very different from those instantly claimed. In fact, some of the originally disclosed pore sizes and all of the originally disclosed particles sizes overlap with those of Shio (see pars. [0067] and [0072] of the published application). Thus, while applicants have mixed and matched particle size values from their disclosure in an attempt to navigate around the disclosure of Shio, it is an important point that no evidence of superiority, criticality, or unexpected results has been presented for the instantly claimed range(s). A proper showing would compare the instantly claimed particle sizes with particle size

values outside the claimed range (i.e. those taught by Shio and those originally disclosed by applicants) and establish a unique property possessed only by the claimed range. Such has not been done at this time.

Additionally, while applicants continue to allege that sustained release is not achievable with Shio's powders, this assertion goes against Shio's express teachings:

"A mesoporous powder in accordance with the present invention has a protection effect and a controlled release effect for an inner material because the mesoporous powder has a superb oil absorption property and a large pore. Also, the mesoporous powder is expected to apply for a pharmaceutical carrier and a column packing or cosmetics and foods." (col. 9, lines 15-21, emphasis added)

"...the present inventors found that the micelle holding powder in accordance with the present invention had a hexagonal structure as like said mesoporous powder and a function that could gradually release the cationic material which was contained in the pore." (col. 20, lines 48-52; emphasis added).

Thus, applicants' assertion is refuted by Shio's direct teachings. Shio's silicas are clearly suitable for controlled release of the materials carried therein and have superb adsorption properties, in contrast to applicants' assertion.

Claims 1, 7, 10, 12, and new claims 20, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shio in view of YOSHIMOTO (JP 07-173452; Published Jul. 11, 1995; Ref. BB on IDS dated Mar. 10, 2006).

4. Shio discloses mesoporous silica and associated compositions that are useful as a carrier for cosmetics, pharmaceutical drugs and perfumes (abstract; col. 2, lines 24-34; col. 5, lines 57-59; Table 2; claim 1). Shio does not explicitly teach the other supported substances instantly claimed (i.e. menthols, thermal substances, plant polyphenols, and organic colorants). Nonetheless, as stated above, given the state of the art, it would have been *prima facie* obvious to one of ordinary skill in the art at the

time of the invention to select any one of these agents depending on the desired use of the silica composition.

5. For example, Yoshimoto discloses the use of fine porous inorganic particles such as silica to enclose various functional substances including antibacterials, perfumes, biocides, and agricultural chemicals (par. [0001]). Furthermore, Yoshimoto teaches that such use of porous silica is conventional (par. [0002]). Yoshimoto teaches the use of compounds including menthol (a known cooling substance) (par. [0015]) and camphor (par. [0013]), which is a "thermal substance" as defined in par. [0136] of the instant specification (pre-grant publication).

6. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include either menthol or camphor, in the porous silica compositions of Shio to provide a coolant composition, or as a perfume or antimicrobial composition as taught by Yoshimoto. One would have had a high expectation of success in doing so since Shio teaches that the silicas are useful as carriers for cosmetics, pharmaceutical drugs and perfumes. Thus, one would have expected to arrive at functional compositions for any of these purposes by incorporating an appropriate cosmetic or bioactive agent based on the desired use of the composition. The combination of Shio and Yoshimoto renders claims 1, 7, 10, and 12 obvious.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Yoshimoto fails to disclose porous silica as claimed (response, p.

7).

The arguments with respect to Shio have been addressed *supra*, and that discussion is incorporated herein. Shio teaches the use of the claimed porous silica, and renders the claimed composition obvious since no evidence of unexpected results has been presented (let alone evidence commensurate in scope with the claims). Yoshimoto provides the teaching and motivation for a skilled artisan to use menthol or thermal substances as the substance carried by Shio's porous silicas.

Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shio in view of TERASE (JP 05-070120; Published Mar. 23, 1993; Ref. BC on IDS dated Mar. 10, 2006).

7. Shio discloses mesoporous silica and associated compositions that are useful as a carrier for cosmetics, pharmaceutical drugs and perfumes (abstract; col. 2, lines 24-34; col. 5, lines 57-59; Table 2; claim 1). Shio does not explicitly teach porous silicas as carriers for plant polyphenols. Nonetheless, as stated above, given the state of the art, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select any one of these agents depending on the desired use of the silica composition.

8. For example, Teraser discloses the use of porous silica to adsorb turbidity causing substances from beer (pars. [0005], [0006], [0016], and [0018]). The substances taught to be removed by the silica include polyphenols produced from fermentation of barley and hops (i.e. plant polyphenols) (pars. [0002], [0003], [0007], and [0018]). In light of these teachings, it would have been *prima facie* obvious to one

of ordinary skill in the art at the time of the invention to use the porous silicas taught by Shio to adsorb plant polyphenols.

9. If one wanted a means to remove unwanted polyphenols from, for example, beer, one would have been motivated to use the porous silicas of Shio with a high expectation of success since Terasse teaches porous silica is useful for this purpose. The combination of Shio and Terasse renders claims 1 and 13 obvious.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Terasse uses porous silica for a different reason than that of the instant invention (response, p. 7).

The arguments with respect to Shio have been addressed *supra*, and that discussion is incorporated herein. Shio teaches the use of the claimed porous silica, and renders the claimed composition obvious since no evidence of unexpected results has been presented (let alone evidence commensurate in scope with the claims). The intended use of the silica is not afforded patentable weight in the product claims currently under consideration. Moreover, the examiner has detailed a rationale of why an artisan would use porous silicas to carry plant polyphenols (pars. 8-9 of the prior Office Action), and applicants have ignored this rationale.

Claims 1, 2, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shio in view of ANDERSON (U.S. 6,096,469; Issued Aug. 1, 2000).

10. The teachings of Shio are presented *supra*. Shio teaches the use of pigments compositions of the invention (col. 14, line 50). While this teaching alone would be sufficient to guide an ordinary artisan to include an organic colorant in the silica compositions, this rejection is made under obviousness since Shio does not describe such an embodiment sufficiently to be anticipatory.

11. In addition to Shio, Anderson discloses surfactant templated mesoporous (STM) particles as receptors for ink (abstract; col. 1, lines 62-64; col. 2, lines 34-38; claims 1-6 and 14) that may include additional surfactant (i.e. an emulsifier) (col. 10, lines 54-67). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use an organic colorant such as a dye, pigment, or ink as taught by Anderson in conjunction with the porous silicas of Shio. One would have had a high expectation of success since Shio directly teaches the use of pigments.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Anderson does not teach ink supported by porous silica (response, p. 7).

The arguments with respect to Shio have been addressed *supra*, and that discussion is incorporated herein. Shio teaches the use of the claimed porous silica, and renders the claimed composition obvious since no evidence of unexpected results has been presented (let alone evidence commensurate in scope with the claims). Applicants have mischaracterized Anderson's teachings since Anderson *does* teach that

porous silica is a suitable carrier for ink. Applicants provide no citation to support their assertion to the contrary, while the examiner has pointed to specific portions of Anderson to support the fact that Anderson teaches ink supported by porous silica. Thus, applicants' argument is unpersuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application No. 10/588,453

Claims 1-4, 7-14, and 18-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8 of copending Application No. 10/588,453 in view of Shio and Yoshimoto or Terasé or Anderson. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '453 claims renders obvious that of the instant claims. The '453 claims recite substantially the same product, differing mainly in the way the product is used. As stated *supra*, silicas as claimed are well known and claiming a known use for the same is not inventive. The difference between the two claim sets is that the '453 claims do not recite water glass. However, Shio

teaches this element as well as the claimed process for the production of the porous silicas. The substances carried thereon are either taught by the '453 claims or obvious from the other references.

Claims 1-4 and 6-17 are directed to an invention not patentably distinct from claims 1, 2, 4-8 of commonly assigned 10/588453. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/588,453, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments

Applicants request that the double patenting rejections be held in abeyance.

A request to hold a rejection in abeyance is not a proper response to a rejection.

Rather, a request to hold a matter in abeyance may only be made in response to an OBJECTION or REQUIREMENTS AS TO FORM (see MPEP 37 CFR 1.111(b) and 714.02). Thus, the double patenting rejections of record have been maintained as no action regarding these rejections has been taken by applicants at this time.

Summary/Conclusion

Claims 1-4, 7-14, and 18-23 are rejected; claims 5, 6, and 15-17 are cancelled.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful,

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the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KSO/

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611